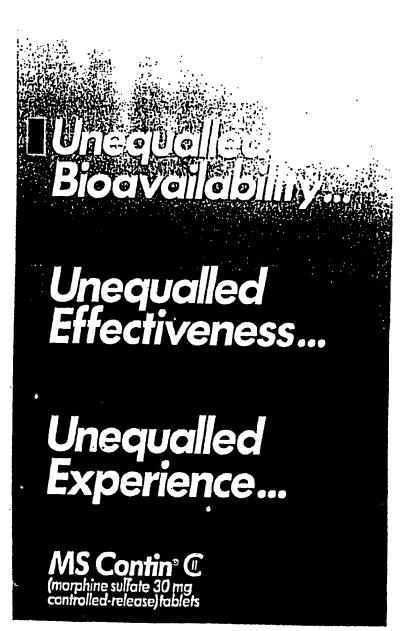
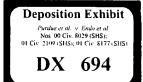


MS Contin is Unequalled...







P 041765

6/19/02

Unequalled Bioavailability...

MS Contin has superior 12-hour bioavailability: MS Contin is 27% more bioavailable than Roxanol SR.

Bioavailability:

"The extent to which a drug reaches its site of action or a biological fluid from which the drug has access to its site of action."

Bioavailability (0-12 hr) of MS Contin 30 mg Tablets vs. Roxanol SR 30 mg Tablets as determined by plasma drug levels in a crossover study in 18 normal volunteerst

MS Contin Tablets

Roxanol SR Tablets!

AUC (0-12 hr; ng/ml × hr)

150

Important Note: While there is an indirect relationship between plasma morphine levels and analgesia, higher plasma levels are nenerally associated with superior relief of natu, as demonstrated in the literature. There is a king time or hysteresis, Individual the time of peak plasma morphine levels and the time of peak drug effects."

12-Hour MS Contin ...

MS Contin (morphine sulfate 30 mg controlled-release) tablets

Document 14-12

- No other morphine product is bioequivalent to MS Contin.
- **I** MS Contin and Roxanol SR are not bioequivalent, therefore, Roxanol SR is not therapeutically interchangeable with MS Contin."
- MS Contin reaches a significantly higher peak concentration, for more effective analgesia.

Bioequivalence:

'They (pharmaceutical formulations) are said to be biologically equivalent if they yield similar concentrations of drug in blood and tissues...Pharmaceutical preparations that are chemically equivalent but not biologically or therapeutically equivalent are said to differ in their bioavailubility."

The three criteria for bioequivalency are comparable	Results of Comparative Study MS Contin Rozanol SR (2 × 30 mg) (2 × 30 mg)
 bioavailability (calculated from area under the time-concentration-curve) 	AUC 147 116
2. time to peak plasma concentration	T _{max} 2.7 2.2 (hrs)
3. peak concentration	Cmox 29 17 (ng/ml)
Time to Peak Concentration (Tmax)*	Peak Concentration (Cmax)
MS Contin	MS Confin
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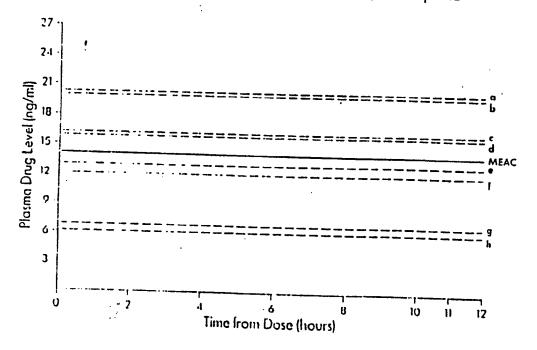
Proven Against Cancer Pain

Unequalled Effectiveness...

What is the effective analgesic level of oral morphine?

A careful review of the literature. Indicates the complexity of defining effective analgesic plasma morphine levels. However, there is generally a "Minimally Effective Analgesic Concentration" (MEAC) of plasma morphine below which no unalgesia is provided (see Chart below).

Minimally Effective Analgesic Concentrations (MEAC) of Morphine



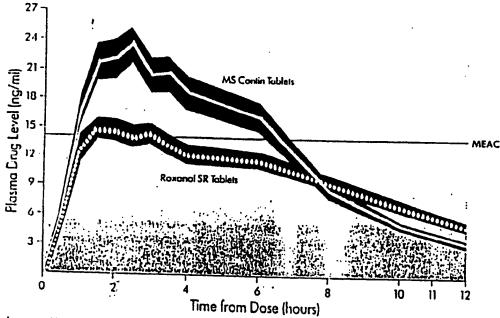
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12-Hour MS Contin ...

MS Contin (morphine sulfate 30 mg controlled-release) tablets

- MS Contin achieves <u>significantly higher</u> analgesic concentrations!
- MS Contin maintains plasma levels above the minimally effective analgesic concentration (MEAC) <u>significantly longer</u>.

Plasma morphine concentration (mean \pm SE) following equal doses of MS Contin and Roxanol SR †



Important Notes: While qualitative differences between morphine formulations are unlikely to vary among subject groups, the absolute immershale of plasma marginus levels and plasmancohimetic parameters observed here as young normal subjects are kiely to be different on those sudder subjects and as proteins with judyanced disease. For example, the apparent plasma morphine elimination half-life can be expected to be protourged in such patients.

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Proven Against Cancer Pain

Unequalled Experience...

- Extensive published clinical documentation that supports 12-hour efficacy and safety¹⁻¹⁴
- Over 6 years' proven clinical experience with over a half-million prescriptions'
- MS Contin has a clinically documented safety profile:

In over 95% of patients, side effects were fewer or equal to pre-study analgesic 15-17

Percent of patients experiencing fewer or equal side effects¹⁵⁻¹⁷

Study #1: Memorial Sloan-Kettering Cancer Center

55% of patients experienced fewer side effects 21% of patients experienced equal side effects

Study #2: New York University School of Medicine

94% of patients experienced fewer side effects 6% of patients experienced equal side effects

Study #3: Bowman Gray School of Medicine

52% of patients experienced fewer side effects 48% of patients experienced equal side effects

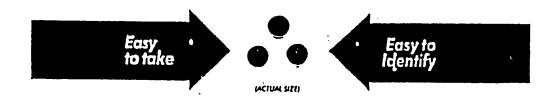
12-Hour MS Contin...

MS Contin (morphine sulfate 30 mg controlled-release) tablets

- MS Contin is the subject of two international symposia on pain control. 18-19
- Safety and efficacy demonstrated at prestigious cancer treatment centers in over 1200 study patients.
- Professional educational support:

 Speakers' Bureau; Educational Slides and Videotapes, including "Cancer Pain Management" Chaired by Dr. Kathleen M. Foley of Memorial Sloan-Kettering Cancer Center.
- MS Contin Tablets are small, round and film coated.

Their distinctive lavender color makes them easy to recognize and identify. Their small size (less than half that of Roxanol SR) makes them easy to swallow.



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Proven Against Cancer Pain

MS Contin[®] is Unequalled...

The only 12-hour oral narcotic analgesic proven against cancer pain.

- Superior 12-hour bioavailability 27% more bioavailable than Roxanol SR.
- No other morphine product is bioequivalent to MS Contin; therefore, none is therapeutically interchangeable.
- Achieves a significantly higher peak concentration for more effective analgesia.
- I Maintains plasma morphine levels above the minimally effective analgesic concentration (MEAC) significantly longer for effective pain relief.
- Published clinical documentation of superior or equal efficacy compared to immediate-release morphine and other oral opioid analgesics.
- Proven safety profile published clinical documentation shows fewer side effects than previous analgesic (Hydromorphone, Methadone, Oxycodone, Codeine, Meperidine).

Also available

MSIR Useful in starting patients on morphine or for treating breakthrough or incident pain. (morphine sulfate) 15 mg and 30 mg lables (#

12-hour MS Contin® @

. (morphine sullate 30 ma controlled-release) tablets

Proven Against Cancer Pain

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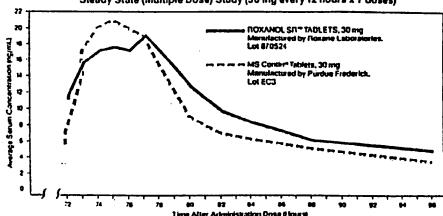
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AVERAGE SERUM CONCENTRATIONS OF MORPHINE FOR ROXANOL SRIMTABLETS AND MS CONTING TABLETS Steady State (Multiple Dose) Study (30 mg every 12 hours x 7 doses)



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Adapted from Abstracts of the 1988 American Society of Clinical Oncologists N

Multiple-dose randomized crossover trial demonstrates Roxanol SR and MS Contin are bioequivalent.

Li Evaluations of standard pharmacokinetic parameters (AUC 79-96 hr, AUC 72-84 hr, Crnax and Cavg) showed less than 10% difference between the two sustained release morphine treatments.

U The investigators concluded that Roxanot SR is bioequivalent to MS Contin.

More cost-effective than MS Contin

☐Roxanol SR offers greater cost containment benefits for hospitals.*

CI Roxanol SR is a greater value for patients who need relief of chronic cancer pain.*



Dosing and Administration

The patients should first be stabilized on Roxanol Concentrated Oral Solution. Convert to Roxanol SR by dividing the total daily Roxanol requirement (an milligrams) by three and administering as Roxanol SR fiablets every eight hours. The dose and dosage schedule can be adjusted for greater flexibility according to severity of pain as well as for the patient's underlying disease, age, and size.

Tablets must be swallowed whole,...not broken, crushed, or chawed. Tablets have a methyl cellulose coating for easier swallowing.

